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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,539	06/19/2006	Andreas Lendlein	26538-0014	6451

24633 7590 10/07/2008  
HOGAN & HARTSON LLP  
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555 THIRTEENTH STREET, N.W.  
WASHINGTON, DC 20004

EXAMINER
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HORNBERGER, JENNIFER LEA

ART UNIT	PAPER NUMBER
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3734

NOTIFICATION DATE	DELIVERY MODE
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10/07/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

dcptopatent@hhlaw.com  
rogruwell@hhlaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/560,539	<b>Applicant(s)</b> LENDLEIN ET AL.	
	<b>Examiner</b> JENNIFER L. HORNBERGER	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06/19/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/19/2006, 11/08/2007</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites the limitation "the biodegradable metal" in line 2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 4-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Igaki (EP 1033145 A1).

Regarding claim 1, Igaki discloses a stent (1) comprising a biodegradable SMP material for use in a nonvascular or vascular field (paragraphs 32 and 36).

Regarding claim 2, Igaki discloses the stent comprises a basic structure of a biodegradable plastic material (paragraph 32).

Regarding claim 4, Igaki discloses the stent comprises additional additives selected among x-ray contrast materials and medically effective compounds (paragraph 68).

Regarding claim 5, Igaki discloses the SMP material is selected from among the following: polymer networks, thermoplastic SMP materials, composite materials and blends (paragraphs 32 and 36).

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Regarding claim 6, Igaki discloses the SMP material is selected from among at least one of the SMP materials in which the SMP effect is induced thermally, is photo-induced, wherein the SMP is biocompatible, haemocompatible, and wherein the SMP reveals a particle free degradation behavior (paragraphs 51-52).

Regarding claim 7, Igaki discloses the network includes at least one of the following: caprolacton units and pentadecalacton units (paragraph 32).

Regarding claim 8, Igaki discloses the network consists of cross-linked caprolactonmacromonomers (paragraphs 32 and 36).

Regarding claims 9 and 10, Igaki discloses the stent comprises a surface coating that modifies haemocompatibility (paragraph 71).

Regarding claim 11, Igaki discloses a method of manufacturing biocompatible SMP materials comprising the processing of SMP material to a stent by one of the following extrusion methods, coating methods, metal casting methods, and spinning and weaving methods (paragraph 33).

Regarding claim 12, Igaki discloses a system, comprising a stent (1) of a biodegradable SMP material (paragraph 36), and including at least one of the following: a temperature controlled balloon catheter and a balloon catheter with an optical fiber (paragraphs 51-52).

Regarding claims 13 and 14, Igaki discloses a method for minimal invasive implantation of a stent, comprising the following steps: placing a stent of a biodegradable SMP material onto a temperature controlled balloon or a balloon catheter with an optical fiber, wherein the SMP material has two shapes in the memory and wherein this material was programmed to two shapes, wherein the first shape, compared to a second shape, is a tubular shape with a larger diameter, inserting the stent to the desired position, wherein the SMP material exists in its

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second shape; heating the stent by inserting a heating medium into the catheter; activating the SMP effect to bring the stent into the first shape, and removing the balloon catheter (paragraphs 51-52).

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harder et al. (US 2004/0098108) in view of Steinke (US 20020103526).

Regarding claims 1 and 3, Harder et al. disclose a self-expanding stent comprising a magnesium alloy, pure magnesium, or a composite of magnesium or a magnesium alloy with biodegradable polymer (paragraph 14). Steinke discloses that it is well known that magnesium alloys are biodegradable (paragraph 37). Therefore, it would have been obvious to one of ordinary skill in the art that the magnesium alloy stent of Harder et al. would also be biodegradable.

***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pathak et al. (US 5,741,323) disclose shape memory induced by introduction of light through a balloon catheter with an optical fiber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. HORNBERGER whose telephone number is (571)270-3642. The examiner can normally be reached on Monday through Friday from 8am-5pm, Eastern time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571)272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

jlh  
09/30/2008

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3731